Applicant: Gary A. Freeman et al. Attorney Docket No.: 04644-068001

Serial No.: 08/962,271

Filed : October 31, 1997

Page: 5

REMARKS

Claims 1-12, 20-22, and 49 have been indicated allowable. Claims 14 and 18 have been indicated as allowable if rewritten in independent form.

Claims 13, 15, 16, 19, 23, 24, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Engel (US 4539996). Claims 23-28, 45, 48, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilman (US 5402884). Claims 16, 17, 19, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilman in view of Engel. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engel in view of Gilman.

Independent claim 13 has been cancelled (without prejudice to its being reintroduced at a latter date in prosecution should the application not be allowed with the claims in their present form). Dependent claim 15 has also been cancelled (with the same reservation as to reintroduction). Dependent claim 14, which the examiner has consistently indicated as allowable since his first office action in this reissue proceeding, has been rewritten in independent form (so that it is identical to claim 14 of the original patent). Dependent claim 50, the other claim dependent on claim 13, has been amended to be dependent on claim 14. Accordingly, claims 14 and 50 are in condition for allowance.

Independent claim 16 and dependent claims 17 and 19 have been cancelled (with the same reservation about reintroduction). Dependent claim 18, which the examiner has consistently indicated as allowable since his first office action in this reissue proceeding, has been rewritten in independent form (so that it is identical to claim 18 of the original patent). Dependent claim 51, the other claim dependent on claim 16, has been amended to be dependent on claim 18. Accordingly, claims 18 and 51 are in condition for allowance.

Independent claim 23 has been amended to more clearly distinguish it from the examiner's prior art. (Applicants reserve the right to return to the original claim should the application not be allowed with claims in their present form.) The claim now calls for a wire lead extending from the electrode, and for the terminal to be nonunitary with that wire lead. One end of the terminal is connected to the wire lead. A second end of the terminal is located at the second end of the connector body (the end isolated from the interior of the compartment).

Applicant: Gary A. Freeman et al. Attorney Docket No.: 04644-068001

Serial No.: 08/962,271

Filed : October 31, 1997

Page: 6

These amendments clearly overcome the anticipation rejections over Engel and Gilman. The examiner was treating the wire lead of Gilman and the electrical conductive trace of Engel as amounting to the claimed terminal. By calling out a separate wire lead, and that the terminal is nonunitary with that wire lead, anticipation is clearly overcome.

Dependent claims 24-25 and 28 have been cancelled (with the same reservation about reintroduction). Minor amendments have been made to claim 27 to make it consistent with amended claim 23. The remaining dependent claims are all dependent on claim 23, and are thus allowable therewith. Accordingly, claim 23 and its dependent claims are in condition for allowance.

Claims 23-48 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in prosecution of the original patent. The examiner has withdrawn two of this three grounds of rejection, but maintained his rejection based on claim 23 not requiring a releasable seal and a barrier element located at the releasable seal,. It is the examiner's position that applicants are now trying to improperly recapture subject matter that they had surrendered to achieve allowance.

Applicant pointed out in the last response that if these were the only changes made in claim 23, then there might possibly be improper recapture, but claim 23 has been narrowed in a another material respect, negating any recapture. Claim 23 requires a connector with one end exposed to the interior of the compartment and a second end isolated from the interior (e.g., exposed to the external environment). With the amendments made in today's response, claim 23 has been further narrowed to require that the connector include a connector body and a terminal, and that the terminal be connected at one end to a wire lead extending from the electrode. These amendments are a material narrowing of the claim, and thus negate recapture.

The examiner is referred to the Federal Circuit's discussion of the recapture doctrine in *Hester Industries, Inc. v. Stein, Inc., 142 F.2d 1427, 46 USPQ2d 1641 (Fed. Cir. 1998)*, where the court indicated that an applicant may

overcome the recapture rule when the reissue claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

Applicant: Gary A. Freeman et al. Attorney 5 Docket No.: 04644-068001

Serial No.: 08/962,271

Filed : October 31, 1997

Page: 7

The limitation to a connector with one end exposed to the interior of the compartment and a second end isolated from the interior is exactly the sort of overlooked aspect that if added to a claim in reissue will negate recapture.

The original application contained FIG. 5 and accompanying description that taught the concept of placing a connector at the periphery of the compartment containing the electrode, wth one end exposed to the interior of the compartment and one end isolated from the interior. That aspect of the invention was independent of the releasable seal and barrier element aspects. Unfortunately, it was overlooked during original prosecution. Applicants are only doing what the reissue process is designed to permit them to do, namely, obtain a patent that covers an aspect of their invention that they had a right to claim, but failed to claim in the original patent.

The examiner's most recent office action takes the position that for a new limitation to qualify as negating recapture it must relate to the same limitation (e.g., a releasable seal or a barrier element) that raised the possibility of recapture. The examiner is urged to reconsider that conclusion, for it is clearly inconsistent with *Hester* and common sense. The examiner's position would make it impossible under any circumstances for an applicant to use reissue to obtain claims to an overlooked aspect of an invention, for by definition a claim to an <u>overlooked</u> aspect of the invention is not going to relate to an aspect that was added to a claim during original prosecution.

Accordingly, claim 23 and its remaining dependent claims are not in violation of the recapture rule, and should be allowed.

Should the examiner maintain his position on recapture, he is urged, for sake of narrowing the issues for appeal, to at least withdraw his prior art rejections.

Attached is a marked-up version of the changes being made by the current amendment. Included for claim 23, for the convenience of the examiner, is the claim as amended in relation to the claim as originally filed and the claim as amended in the last amendment.

Applicant: Gary A. Freeman et al

Serial No.: 08/962,271 Filed

Page : 8

: October 31, 1997

Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Attorney Docket No.: 04644-068001

G. Roger Lee

Reg. No. 28,963

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

20283107.doc

Applicant: Gary A. Freeman et al.

Serial No.: 08/962,271 Filed: October 31, 1997

Page : 9

Attorney s Docket No.: 04644-068001

Version with markings to show changes made

In the claims:

Claims 13, 15, 16, 17, 19, 24-25, and 28 have been cancelled (without prejudice).

Claims 14, 18, 23, 27, 42, 50, and 51 have been amended as follows:

-- 14. (Amended) An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a first adhesively-applied skin electrode,

a first compartment containing said first electrode,

<u>a releasable seal adapted to seal said first compartment and maintain said first electrode</u> in a sealed mode in which said first electrode is not exposed to an external environment,

a connector of said first electrode,

a second compartment outside of said first compartment and containing said connector of said first electrode, and

a barrier element positioned at said releasable seal and providing an electrically conductive path between the first electrode and the connector without exposing the first electrode to the external environment,

[The electrode package of claim 13,]

wherein said barrier element comprises a layer of material formed around a wire lead of said first electrode, the wire lead providing the electrically conductive path between said first electrode and the connector.

- 18. (Amended) An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:
 - a first adhesively-applied skin electrode,
 - a compartment containing said first electrode,
- a releasable seal adapted to seal said compartment and maintain said first electrode in a sealed mode in which said first electrode is not exposed to an external environment,



Applicant: Gary A. Freeman et al.

Serial No.: 08/962,271

Filed : October 31, 1997

Page :

. 10

Attorney Docket No.: 04644-068001

a connector of said first electrode, the connector comprising at least one terminal adapted to make and break an electrical connection, and the connector being exposed to the external environment, and

a barrier element positioned at said releasable seal and providing an electrically conductive path between said first electrode and said connector of said first electrode without exposing the first electrode to the external environment.

wherein said barrier element comprises a layer of material formed around a wire lead of said first electrode, the wire lead providing the electrically conductive path between said first electrode and the connector,

[The electrode package of claim 17,]

wherein the layer of material includes an arcuate upper portion and an arcuate lower portion, said barrier element being formed by heat sealing a first wall of the compartment to the arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

Amendments shown in relation to last amendment:

23. (Third Amendment) An electrode package in which one or more adhesively-applied skin electrodes may be sealed, the electrode package comprising:

an adhesively-applied skin electrode,

a wire lead extending from the electrode,

a compartment containing the electrode <u>and wire lead</u> and maintaining the electrode <u>and</u> <u>wire lead</u> in isolation from an external environment, and

a connector electrically connected to the electrode, the connector comprising at least one terminal and a connector body supporting the terminal, [and]

the connector body comprising [including]

a first end exposed to an interior of the compartment and in isolation from the external environment[,] and

a second end isolated from the interior of the compartment when the compartment maintains the electrode in isolation from the external environment,

the terminal being nonunitary with the wire lead, and comprising

Applicant: Gary A. Freeman et al. Attorney Docket No.: 04644-068001

Serial No.: 08/962,271

Filed : October 31, 1997

Page: 11

a first terminal end connected to the wire lead and

a second terminal end located at the second end of the connector body,

the connector providing an electrically conductive path to the electrode from the second terminal end outside the compartment when the compartment maintains the electrode in isolation from the external environment.

Amendments in relation to claims as originally filed:

23. (Third Amendment) An electrode package in which one or more adhesively-applied skin electrodes may be sealed, the electrode package comprising:

an adhesively-applied skin electrode,

a wire lead extending from the electrode,

a compartment <u>containing the electrode and wire lead and [for]</u> maintaining the electrode and wire lead in isolation from an external environment, and

a connector electrically connected to the electrode, the connector [and] comprising at least one terminal and a connector body [including] supporting the terminal,

the connector body comprising

a first end exposed to an interior of the compartment and in isolation from the external environment[,] and

a second end isolated from the interior of the compartment when the compartment maintains the electrode in isolation from the external environment,

the terminal being nonunitary with the wire lead, and comprising

a first terminal end connected to the wire lead and

a second terminal end located at the second end of the connector body,

the connector [body] providing an electrically conductive path to the electrode from the second terminal end outside the compartment when the compartment maintains the electrode in isolation from the external environment[,

wherein

the electrode is positioned in the compartment and isolated from the external environment,

Applicant: Gary A. Freeman et a

Serial No.: 08/962,271

4: 'October 31, 1997 Filed

Page

the electrode is removable from the compartment to expose the electrode to the external environment, and

Attorney's Docket No.: 04644-068001

the connector maintains the electrical connection to the electrode when the electrode is removed from the compartment].

- 27. (Amended) The electrode package of claim 23 [26], wherein the connector further comprises [first and second] a second terminal[s] with an end extending from the second end of the connector body, wherein an electrically conductive path is provided between the [first electrode and the first terminal and between the second electrode and the end of the second terminal when the compartment maintains the electrodes in isolation from the external environment.
- 42. (Amended) The electrode package of claim 23[, further comprising a wire lead extending from the electrode to the second end of the connector body, the wire lead being positioned within the compartment and providing the electrical connection between the electrode and the connector,] wherein the connector body includes strain relief elements for relieving strain on the wire lead.
- 50. (Amended) The electrode package of claim 14 [13] in combination with a defibrillator, wherein the first adhesively-applied skin electrode comprises a defibrillation electrode and the connector and defibrillator are connected to provide an electrically conductive path between the defibrillator and the electrode while the releasable seal maintains the electrode in the sealed mode in isolation from the external environment.
- 51. (Amended) The electrode package of claim 18 [16] in combination with a defibrillator, wherein the first adhesively-applied skin electrode comprises a defibrillation electrode and the connector and defibrillator are connected to provide an electrically conductive path between the defibrillator and the electrode while the releasable seal maintains the electrode in the sealed mode in isolation from the external environment. --